REMARKS

Claims 47-63 are pending. Claims 47-49 and 61-63 are under examination, insofar as they read on non-polypeptide antagonists (as elected in response to restriction).

Rejections Under 35 U.S.C. §112, First Paragraph

Enablement

Claims 47-49 and 61-63 are rejected as "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." The Examiner provides the following grounds for the rejection:

> The instant claims are similar to a single means claim in that they require the administration of an MCH antagonist, wherein the antagonist is a non-polypeptide drug or chemical and wherein the antagonist binds an MCH receptor. MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in In re Hyatt, 708 F.2d 712, 218. (Office action at pages 2-3, emphasis added)

The Examiner concludes that the present claims are "comparable to Hyatt" and therefore not enabled. This rejection is respectfully traversed.

The present claims are clearly not single means claims. As the Examiner acknowledges, a single means claims covers "every conceivable means for achieving the stated purpose." In contrast, the claims under examination (a) recite a narrow stated purpose (inhibiting appetite or weight gain) and (b) recite specific structural and functional limitations of the agent (or "means", to use the Examiner's phraseology) to be used to inhibit MCH signaling. For the claims in the present application to cover "every conceivable means for achieving the stated purpose," a hypothetical claim would have to read: "a method of inhibiting weight gain comprising administering an agent to inhibit weight gain" or "a method of inhibiting MCH signaling comprising administering an MCH antagonist." Indeed, the claim at issue in In re Hyatt was very much like these hypothetical claims. The In re Hyatt claim read as follows:

> 35. A Fourier transform processor for generating Fourier transformed incremental output signals in response to incremental input signals, said Fourier transform processor comprising incremental means for incrementally generating the Fourier transformed incremental output signals in response to the incremental input signals.

Clearly, unlike the present claims, the Hyatt claim was extremely broad and completely circular, defining the "means" and the "stated purpose" in the same way: generating Fourier transformed incremental output signals in response to incremental input signals. The present claims are substantially narrower than those of In re Hyatt. In sharp contrast to the In re Hyatt claim, the present claims narrowly recite administering a non-polypeptide MCH antagonist that binds a specific receptor, the MCH receptor to achieve the stated means of inhibiting weight. Not only do the present claims not cover every means for inhibiting weight, they do not cover the majority of possible means or agents that could inhibit weight. In fact, the present claims do not even cover the majority of agents that could antagonize MCH signaling. For example, the presently elected claims do not cover any antisense or RNAi agents, anti-MCH antibodies or MCH receptor (MCHR) fragments or mimetics, all of which would antagonize MCH signaling to inhibit weight gain, and none of which would fall under the structural and functional limitations of the antagonist recited in the claims. Thus, the present claims cannot be said to be single means claims and In re Hyatt does not support the nonenablement of the present claims.

The Examiner also argues that "screening for bioactivity could be done, however, this is basically a 'wish to know' and the standard for an enabling disclosure is not one of making and testing." The Examiner then cites Amgen v. Chugai, 18 USPQ 2d 1016, to support this proposition. At the outset, Applicants note that the portion of Amgen v. Chugai that the Examiner has cited does not relate to the enablement requirement, but rather to conception. Further, unlike the present invention, Amgen v. Chugai was concerned with conception of a claimed composition or compound, namely a gene. The present claims are not directed to compounds. Rather, they are directed to methods of inhibiting weight gain. Therefore, the present claims are substantially narrower in scope than the claims at issue in Amgen. That is, the present claims do not cover or dominate (nor would they prevent the patenting of) claims to non-polypeptide compounds that bind MCH receptor. Nor would they cover, dominate, or prevent

the patenting of, any other uses of such compounds. The present claims only cover a narrow, specific use for such compounds, namely to inhibit appetite or weight gain. Thus, the scope of the present claims is much narrower than the scope of the claims at issue in Amgen v. Chugai, in which the claims covered (and would have dominated) all EPO encoding DNAs (compositions) and all methods of use of such DNA compositions. Therefore, because the scope of the claims in the present case is so much narrower than the claims in Amgen v. Chugai, the scope of enablement required is narrower as well.

The enablement requirement is satisfied if an ordinary skilled artisan could practice the claimed methods. Using routine methods such as those provided in the specification or very similar methods, other investigators have been able to identify non-polypeptide MCH antagonists that bind competitively to the MCH receptor and perform the claimed methods. For example, as discussed in the declaration of Dr. Maratos-Flier filed on April 18, 2002, Takekawa et al. (2002) European J. Pharmacol. 438:129-135 used a combination of in vitro and in vivo testing, very similar to the methods taught in the specification, to identify the non-polypeptide MCH antagonist T-226296 from a library of chemical compounds. This provides clear evidence that the specification is enabling for the present claims.

In light of the foregoing, Applicants respectfully request that the rejection be withdrawn.

Written Description

Claims 47-49 and 61-63 are rejected as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner provides the following reasoning:

> First, the claims provide no structure for the compounds which are encompassed in the claimed method, except that the compounds are not polypeptides. (Office action, page 5)
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> Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. . . .The instant claims are directed to drugs and/or chemicals, which could be identified by screening, but for which, there is no written description. (Office Action, pages 7-8, citing Fiers v. Revel, Amgen v. Chugai, and Fiddes v. Baird)

This rejection is respectfully traversed. Applicants note once again that, contrary to the Examiner's above-quoted statement, the instant claims are not directed to drugs and/or chemicals. The present claims are directed to methods of inhibiting appetite or weight gain. The cases cited by the Examiner (Fiers, Amgen, and Fiddes) all relate to the written description requirement for composition claims wherein the invention resides in the structure of the compound. In each of these cases, the claims at issue related to novel DNA or protein sequences. There is no indication in these cases that their holdings extend to method claims where the inventive and claimed concept is inhibiting a specific biological interaction to achieve a previously unknown result (in this case, weight loss). Although there is only one standard for written description, the Examiner's reasoning demands the same result when the standard is applied to two very different fact patterns. The Examiner's application of the standard would deprive an inventor who discovered that inhibiting a particular pathway causes a vitally important result of any but trivial patent protection. The present invention, which is that antagonizing the MCH receptor inhibits weight gain, is properly described. Requiring a written description of compounds that might be discovered in the future is not required by the patent law.

Indeed, the Federal Circuit has recently, in Amgen Inc. v Hoechst Marion Roussel (314 F.3d 1313, Fed. Cir. 2003) limited the holding of Eli Lilly v. The University of California (119 F.3d 1559, Fed. Cir. 1997), a case which is a progeny of the Fiers and Amgen line of cases cited by the Examiner, to its facts, i.e., to claims directed to gene sequences. Indeed, the dissent in Amgen v. Hoechst notes:

> Eli Lilly articulated two principles of the written description requirement: that in haec verba description of broadly described generic subject matter may not suffice to describe the subject matter of that particular claim, 119 F.3d at 1567, 43 USPQ2d at 1404-05, and that disclosure of a species may not suffice to describe a genus, id. at 1568-69, 43 USPQ2d at 1405-06. The district court followed neither of these principles here, and the majority, dismissing Eli Lilly on the grounds that **no undisclosed DNA molecule appears in this case**, verges on confining Eli Lilly to its facts. (Amgen, 314 F.3d at 1361)

Accordingly, the case law cited by the Examiner is not particularly informative on the written description requirement for method claims such as the instant claims.

Furthermore, the present claims satisfy the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement (the Guidelines). The Guidelines state that:

> [f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the method of making the claimed invention. (66 Fed. Reg. 1099, Jan. 5, 2001, emphasis added).

The present claims recite both structural and functional limitations sufficient to satisfy the written description requirement. The claims are limited functionally in that they require that the agent administered in the claimed methods be an MCH antagonist. The claims are limited structurally in that the antagonist is a non-polypeptide agent and binds to a specific protein, i.e., an MCH receptor. Clearly, binding to a specified receptor imparts a specific structure to the antagonist recited in the claims. Thus, one of ordinary skill in the art would understand that Applicants were in possession of the claimed methods.

Accordingly, Applicants respectfully request that the rejection be withdrawn.